



**PRESBYTERIAN
INTERCOMMUNITY
HOSPITAL**

A Regional Hospital and Health Center

7937 55 FEB 13 21 25

*12401 Washington Boulevard
Whittier, California 90602-1009
(562) 698-0811
Hearing Impaired TDD (562) 696-9267*

December 1, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 106 1
Rockville, MD 20852

RE: Docket No: 97N-484S
Regulation of Allograft Materials

I am writing to disagree with the proposal of regulation of bone allograft material by the FDA. The bone grafts that we have used over the years have been an excellent resource for patients, and vary significantly, in size, shape and type of graft for a variety of orthopaedic applications. I do not feel that FDA assessment and clinical trials and regulatory documentation is appropriate for these bone graft substitutes that are tissue and not a device.

Sincerely,

Susan M. Swank, M.D.
Medical Director

97N-484S

C100



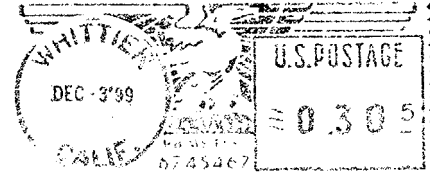
**PRESBYTERIAN
INTERCOMMUNITY
HOSPITAL**

A Regional Hospital and Health Center

*12401 Washington Boulevard
Whittier, California 90602-1099*

**RETURN SERVICE
REQUESTED**

**POSTED
FIRST CLASS**



****12-0-99 LOS ANGELES CA 90000**

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

